

REMARKS

This Application has been carefully reviewed in light of the Final Office Action mailed October 13, 2006 and Advisory Action mailed December 19, 2006. At the time of the Office Action, Claims 1-3, 6-7, 10-19, 22-23, 26-39, 42 and 45-57 were pending in this Application. Claims 1-3, 6-7, 10-19, 22-23, 26-39, 42 and 45-57 were rejected. Applicant's Amendment and Response filed November 30, 2006 sought to add new claims 58-63, but the Advisory Action denied entry of these claims.

Applicant has herein cancelled all previously pending claims, namely claims 1-63 without prejudice or disclaimer in favor of new claims 64-96. More specifically, claims 1-3, 6, 7, 10-16, 48, 50, 52, 58, and 59 have been cancelled in favor of new claims 64-78 and claims 17-19, 22, 23, 26-36, 51, 54, 60, and 61 have been cancelled in favor of new claims 79-96.

New claims 64-96 are fully supported by the application as originally filed. For example, new claims 64-96 are supported, at least in part, by the corresponding original claims.

New claims 64, 67, 79, and 82 each recite "from about 0.1 M to 1.0 M of a chelator enhancing component." Support for this range may be found in the application as originally filed. For example, the following support may be found in the application (page:lines):

3:24-25	"...from about 0.1M to 2M."
3:25	"...at least 1M..."
4:10-11	"...e.g., in the range of from about 0.1M to 2M..."
6:31	"...generally in the range of from about 0.1M to 2M..."
7:1-2	"...at least 1M."
10:19-20	"i.e., 1M sodium perchlorate..."
11:27-28	a 1:10 dilution of "...1M guanidine HCl..."
11:27-29	a 1:10 dilution of "...1M sodium perchlorate..."
11:27-29	a 1:10 dilution of "...1M sodium thiocyanate..."
11:27-30	a 1:10 dilution of "...1M lithium chloride..."

Applicant respectfully invites the Examiner's attention to the description of Figure 8 (11:25 to 12:2), which indicates that a composition with 1M chelator enhancing component is diluted ten-fold, *i.e.*, producing a final concentration of 0.1M. Accordingly, the range of

from about 0.1 M to about 1.0 M is fully supported by the specification as originally filed and does not constitute new matter.

New claims 66 and 81 recite “contacting the test sample with a buffer.” Support for this amendment may be found in the application as originally filed, for example, at page 8, lines 1-4 and page 15, line 23. Therefore, this amendment does not constitute new matter.

New claims 77 and 95 recite “a polymerase chain reaction, a ligase chain reaction, nucleic acid sequence-based amplification, strand displacement amplification, and a genetic transformation test.” Support for this amendment may be found in the application as originally filed, for example, at page 5, lines 17-22. Therefore, this amendment does not constitute new matter.

In view of the cancellation of all previously pending claims, Applicant believes that all outstanding rejections and objections are moot. Nevertheless, Applicant will address the rejections in light of the new claims.

Applicant respectfully requests reconsideration and favorable action in this case.

Double Patenting Rejection

The Examiner provisionally rejected Claims 1-16 and 52-53 based on the judicially created double patenting doctrine over Claims 1-8 of related U.S. Patent No. 6,458,546 (hereinafter “‘546 patent”) stating that the subject matter claimed in the instant application is fully disclosed in the referenced patent.

The Examiner provisionally rejected Claims 17-48, 50-51 and 54-57 based on the judicially created double patenting doctrine over Claims 1-8 of related U.S. Patent No. ‘546 patent, in view of International Application No. WO 93/03167 by David S. Sigman (“*Sigman*”), stating that the subject matter claimed in the instant application is fully disclosed in the referenced patent.

Applicant respectfully traverses the rejection. However, to reduce the cost and time required to obtain patent protection, a Terminal Disclaimer filed in compliance with 37 C.F.R. 1.321 is attached hereto. The Terminal Disclaimer is offered in the event the Examiner converts the provisional rejection to a rejection based on non-statutory double patenting grounds. The ‘546 patent and the instant patent application are commonly owned by Sierra Molecular Corporation.

Rejections under 35 U.S.C. § 112

Claims 1-3, 6-7, 10-19, 22-23 26-39, 42 and 45-47 were rejected by the Examiner under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection and submits that claims 64-96 fully comply with the written description requirement. Specifically, the range of “from about 0.1 M to 1.0 M of a chelator enhancing component” recited by new claims 64, 67, 79, and 82 is described in the application in sufficient detail to convey to one of ordinary skill in the art that Applicant possessed this range at the time the application was filed. For example, the specification discloses that stock reagents with 1 M of a chelator enhancing component may be diluted ten-fold resulting in a 01.M composition. *See* page 11, lines 27-30. This rejection is, therefore, moot as to the cancelled claims and inapplicable and/or overcome as to the new claims. Accordingly, this rejection should be removed and/or withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-3, 6, 10-13, 15-19, 22, 26-29, 31-39, 46-48 and 50-57 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by International Application No. WO 95/35390 by David Y. Zhang (“*Zhang*”) as evidenced by U.S. Patent No. 6,168,922 issued to Michael A. Harvey et al. (“*Harvey*”) or U.S. Patent No. 5,939,259 issued to Michael A. Harvey (“*Harvey* ‘259”) or U.S. Patent No. 5,763,185 issued to Matthew P. Collis et al. (“*Collis*”). Applicant respectfully traverses and submits the cited art does not teach all of the elements of the claimed embodiment of the invention. Applicant cancels all pending Claims and submits new Claims 64-87 to overcome the rejections under 35 U.S.C. §102(b).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “the identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully submits that the art cited as anticipatory by the Office Action cannot anticipate the rejected Claims, because it fails to teach all the elements of the present Claims.

Zhang appears to disclose a method of lysing a pathogenic microorganism using equal volumes of sample and lysis buffer. *See Zhang*, page 14, lines 14-21. In addition, *Zhang*

appears to disclose that “a suitable lysis buffer for use in the present method comprises 2.5 - 5M guanidine thiocyanate (GnSCN), 10% dextran sulfate, 100mM EDTA, 200 mM Tris-HCl (pH8.0) and 0.5% NP-40.” *See Id.* at page 14, lines 21-25.

Zhang, however, fails to teach at least three elements of claims 64 and 79. First, *Zhang* fails to teach “from about 0.1 M to 1.0 M of a chelator enhancing component.” As acknowledged by the Office Action, *Zhang* teaches (at most) that its lysis buffer has a guanidine thiocyanate concentration of 2.5 - 5.0M, which clearly does not overlap with the instantly recited range. Applicant respectfully contends that the diluted concentration (*i.e.*, after *Zhang*’s lysis buffer is combined with an equal volume of sample) is not relevant since the range recited by the instant claims is that of the reagent prior to being combined with a test sample. In addition, Applicant respectfully asserts that the composition of the lysis buffer is not relevant since that composition cannot suppress interference attributable to a masking agent, *i.e.*, because hybridization has occurred (page 17, lines 18-26) and the masking agents have been removed (page 17, line 28 to page 18, line 1) at that point of *Zhang*’s method. Therefore, *Zhang* fails to teach the recited range.

Zhang also fails to teach “a reagent consisting of...a chelator and...a chelator enhancing component” as recited by claims 64 and 79. On the contrary, *Zhang* teaches that dextran sulfate, Tris-HCl, and NP-40 are required components of the lysis buffer (page 14, lines 14-25) and that Tris-HCl and NP-40 are required components of the wash buffer (page 18, lines 5-9). Finally, *Zhang* fails to teach “a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, and combinations thereof” as recited by claims 64 and 79. Indeed, *Zhang* fails to teach a chaotropic agent other than guanidine thiocyanate. None of the allegedly supporting reference cited by the Office Action constitute evidence to the contrary. For example, *Harvey, Harvey* ‘259, and *Collis* all fail to teach that guanidine thiocyanate is the same as or includes lithium chloride and/or sodium salicylate. Therefore, *Zhang* fails to anticipate claims 64-66 and 79-81.

Similarly, *Zhang* fails to teach at least two elements of independent claims 67 and 82. First, *Zhang* fails to teach “from about 0.1 M to 1.0 M of a chelator enhancing component” for the same reasons set forth above with respect to claims 64 and 79. Second, *Zhang* fails to teach “a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, sodium perchlorate, sodium thiocyanate, and combinations thereof” as recited by claims 67 and 82. None of the allegedly supporting reference cited by

the Office Action constitute evidence to the contrary. For example, *Harvey, Harvey* '259, and *Collis* all fail to teach that guanidine thiocyanate is the same as or includes lithium chloride, sodium salicylate, sodium perchlorate, and/or sodium thiocyanate. Since *Zhang* fails to teach each and every limitation of claims 67-78 and 82-96, *Zhang* fails to anticipate these new claims. This rejection is, therefore, moot as to the cancelled claims and inapplicable and/or overcome as to the new claims. Accordingly, this rejection should be removed and/or withdrawn.

Rejections under 35 U.S.C. §103

Claims 14, 30 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Zhang* in view of U.S. Patent No. 5,973,137 issued to Ellen M. Heath ("Heath"). Applicant respectfully traverses and submits the cited art combinations, even if proper, which Applicant does not concede, does not render the claimed embodiment of the invention obvious. Applicant cancels all pending Claims and submits new Claims 64-96 to overcome the rejections under 35 U.S.C. §103(a).

Claims 7, 23 and 42 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Zhang* in view of U.S. Patent No. 5,030,720 issued to Alexander U. Bertland II et al. ("Bertland"). Applicant respectfully traverses and submits the cited art combinations, even if proper, which Applicant does not concede, does not render the claimed embodiment of the invention obvious. Applicant cancels all pending Claims and submits new Claims 64-96 to overcome the rejections under 35 U.S.C. §103(a).

In order to establish a *prima facie* case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

As set forth in the preceding section, *Zhang* fails to teach or suggest each and every element of the instant claims. With respect to claims 64-66 and 79-81, *Zhang* fails to teach or suggest:

- (a) "from about 0.1 M to 1.0 M of a chelator enhancing component;"
- (b) "a reagent consisting of...a chelator and...a chelator enhancing component;" and
- (c) "a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, and combinations thereof."

With respect to claims 67-78 and 82-96, *Zhang* fails to teach or suggest:

- (a) "from about 0.1 M to 1.0 M of a chelator enhancing component;" and
- (b) "a chelator enhancing component selected from the group consisting of lithium chloride, sodium salicylate, sodium perchlorate, sodium thiocyanate, and combinations thereof."

The Office Action has not alleged that *Heath* supplies any of these disclosures. Indeed, Applicant respectfully asserts that *Heath* does not. Moreover, neither *Zhang* nor *Heath* furnish the required motivation to combine or reasonable expectation of success. Therefore, claims 64-81 are nonobvious over *Zhang* in view of *Heath*.

Similarly, the Office Action has not alleged that *Bertland* supplies any of these disclosures. Indeed, Applicant respectfully asserts that *Bertland* does not. Moreover, neither *Zhang* nor *Bertland* furnish the required motivation to combine or reasonable expectation of success. Therefore, claims 64-81 are nonobvious over *Zhang* in view of *Bertland*.

This rejection is, therefore, moot as to the cancelled claims and inapplicable and/or overcome as to the new claims. Accordingly, this rejection should be removed and/or withdrawn.

Request for Continued Examination (RCE)

Applicant encloses a Request for Continued Examination (RCE) Transmittal, along with a check in the amount of \$790.00 for the RCE fee.

CONCLUSION

Applicant has made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicant respectfully requests reconsideration of the pending claims.

Applicant authorizes the Commissioner to charge \$790.00 for the RCE fee, \$130 for the Statutory Disclaimer fee and \$1020.00 for the Three-Month Extension fee. Applicant believes there are no further fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at 512.322.2647.

Respectfully submitted,
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Enclosures: 1) Request for RCE Transmittal
2) Petition for Three-Month Extension
3) Fee Transmittal for Statutory Disclaimer